REMARKS

The claims have been amended to limit the albumin in the albumin preparation of the present invention to human serum albumin (HSA). Support for this limitation is found throughout the specification of the present application including, inter alia, the paragraph bridging pages 7 and 8. This amendment does not raise new issues and would not require further search because the rejections of the claims are not dependent on the type of albumin contained in the claimed albumin preparation.

Claim Rejections - 35 U.S.C. §102

Claims 1-3 and 8 are rejected under 35 U.S.C. §102(b) as being anticipated by EP 0 683 233 ("EP '233"). The Examiner's position is that the rejected claims read on the composition disclosed in EP '233.

The issue raised by the 35 U.S.C. § 102(b) rejection is whether the culture medium of EP '233 includes each of the limitations recited in claims 1, 2, 3 and 8.

Regarding this issue, the claims require that the albumin preparation be "in a form suitable for administration to a patient." This is a positive limitation that excludes ingredients that cannot be reasonably included in a composition (preparation or medium) useful for administration to a patient, i.e., a human.

The Office has taken the position in the Action (see, for example, the paragraph bridging pages 7 and 8) that the recitation in claim 1 of the albumin preparation "being in a form suitable for administration to a patient for treatment of liver diseases" is a recitation of an intended use that is given little or no weight in distinguishing over the prior art. The position is not correct because, as noted above, the recitation "[the preparation] being in a form suitable for administration to a patient" is not an intended use - it is a limitation on the components that can be contained in the preparation. The further recitation "for treatment of liver diseases", even if considered an intended use of the preparation, does not diminish the weight to be given to the requirement that the preparation be in a form, or contain components, suitable for administration to a patient.

The culture medium disclosed in EP '233, i.e., the culture medium identified in Table 1 which is the only specific culture medium disclosed in EP '233, is not in a form suitable for administration to a patient because the culture medium includes components that would be harmful to a patient. For example, the medium includes methanol. Methanol is harmful to the optic nerve. The lethal dose of methanol is no more than 1g/kg. The pharmacological affect to a patient of an administration of yeast

extract or peptone has not been confirmed and, thus, these components cannot be said to be suitable for administration to a patient.

For the above reasons, the culture medium contained in EP '233 does not meet each of the limitations recited in claim 1. EP '233, therefore, does not place the albumin preparation claimed in claim 1 (or any of the claims dependent thereon) in the hands of the public and cannot properly support a rejection of the claims for anticipation under 35 U.S.C. § 102.

It is also noted for the record with respect to the limitations recited in claims 2 and 8 that EP'233 does not disclose the concentration of HSA in the culture medium and does not disclose a sterilized aqueous solution of the culture medium. EP '233 discloses only an amino acid-containing medium for producing recombinant HSA (human serum albumin) by culturing an HSA-producing host, prepared by gene manipulation techniques (as described on page 2, lines 29-31, from page 3, line 43 to page 4, line 24, and in Example 1).

Removal of the 35 U.S.C. § 102(b) rejection is in order and is respectfully requested.

Claim Rejections - 35 U.S.C. §103

Claims 1-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over EP '233 taken with WO 88/01861 ("WO '861") or Ohashi et al. (U.S. Patent No. 4,499,076) ("Ohashi").

Initially, it is noted that the Office, in view of its position that the recitation "being in a form suitable for administration to a patient for treatment of liver diseases" is only a statement of intended use, has not identified any teaching, suggestion or motivation in the prior art to remove those components from the culture medium of EP '233 that make the medium not suitable for administration to a patient. However, for the reasons explained above, the recitation "in a form suitable for administration to a patient" is a limitation that excludes components from the preparation of the present invention that are not suitable for administration to a patient. Therefore, the Office must show a teaching, suggestion or motivation in the prior art to modify the medium of EP '233 to make it suitabler for administration to a patient. In the absence of such a showing, the 35 U.S.C. § 103(a) rejection is improper and should be removed.

Regarding claim 7, this claim recites a method of treating liver diseases by administering the albumin preparation of claim 1 to a patient in need of such treatment. The Office, in the last

paragraph on page 8, states that "the addition of albumin into an amino acid preparation containing branched amino acids of the primary reference would improve in restoring the concentration of albumin to a normal status because the secondary reference of Ohashi et al. has shown that the administration of nutritional composition containing various branched amino acids, carbohydrates, fats, vitamins and minerals would result in treating liver diseases ...". The position of the Office is not understood because the Office does not explain what is meant by "restoring the concentration of albumin to a normal status." The "normal status" of what? The culture medium of EP '233 does not have a normal status of albumin. Moreover, the position of the Office does not address the relevant issue of whether it would have been obvious to a person of ordinary skill in the art to modify the culture medium of EP '233 and administer the culture medium to a person in need of treatment of a liver disease. Moreover, the Office has not explained why a person of ordinary skill in the art would be motivated to administer a **culture medium** as disclosed in EP '233, with or without an addition of albumin, to a patient.

A proper analysis of obviousness under §103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they

should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *See In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529 (Fed. Cir. 1988). The Office has not provided any reasoning showing that a person of ordinary skill in the art would have had a reasonable expectation of success of administering the culture medium of EP '233, modified as proposed by the Office, to a patient for any purpose and, particularly, for the treatment of liver diseases. EP '233 discloses nothing concerning the effects of the medium disclosed therein on liver diseases and does not disclose a preparation for treatment of liver diseases. Ohashi, merely discloses a diet containing amino acids for liver diseases and also discloses nothing concerning the effect of the other components of the culture medium of EP '233 on liver diseases. Additionally, none of the art suggests the removal of harmful components from the culture medium of EP '233 and the use of the so-modified medium for the treatment of liver diseases as recited in claim 7.

Removal of the 35 U.S.C. § 103(a) rejection is also in order and is respectfully solicited.

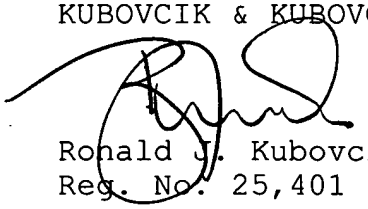
The foregoing is believed to be a complete and proper response to the Office Action dated April 7, 2004, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK



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